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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,051	12/13/2000	Hua Zhu Ke	PC9344BRTR	6748

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/736,051	KE ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30,33-42,45-50,52-62,65-69 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *46-50,52-62,65-69 and 72* is/are allowed.

6)☒ Claim(s) *1,2,11,12,30,33-42 and 45* is/are rejected.

7)☒ Claim(s) *3-10 and 13-29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Please note that the Examiner in this case has changed. Please refer to the conclusion of this Office Action for the Examiner's name and contact information.

The Finality of the previous Office Action is hereby REMOVED and a new, Non-Final Office Action is set-forth *infra.*

Claims 1-30, 33-42, 45-50, 52-62, 65-69 and 72 are pending in the application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 11-12, 30 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F. 3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

"If the current invention is a telescope and you look through the telescope to see 'things' at the other end, you may be said to reach-through to those 'things' - for example, to a star that you can see. Information is being provided through the telescope to define the star, at the other end, but the inventor of the telescope does not

possess the star seen through the telescope" . Lim et al. (2005) (see: www.law.unimelb.edu.au/ipria/ publications/workingpapers/IPRIA%2003.05.pdf). It is further deemed, and made clear in the Instant specification, that the identification of such compounds/compositions as broadly claimed would not be certain; on the contrary, one would need to ***arbitrarily*** test a compounds/composition in order to verify its effectiveness as an estrogen agonist/antagonist as well as a prostaglandin agonist/antagonist as Instantly claimed.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient" MPEP § 2163.

The MPEP further states that if the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus MPEP § 2163. Although the MPEP does not define what constitutes a sufficient number of representative species, the courts have indicated what does not constitute a representative number of species to adequately describe a broad generic: *In Gostelli*,

the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618. T he MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 1-2, 11-12, 30 and 33 are a broad generics, with respect to *all possible* estrogen agonists/antagonists and/or all prostaglandin agonists/antagonists. The possible structural variations are limitless to *any* class of therapeutic compound as is clearly evidenced by the Instant claims which provide for vastly different compounds which fulfill the requirements of being an estrogen agonist/antagonist for example (e.g., raloxifine and Cis-6-(4-hydroxyphenyl)-5-[-4-(-2-piperidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol). The specification lacks sufficient variety of species of to reflect this variance in the genus.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachmann, G.A (1994).

According to Bachmann, G.A. (1994), Tamoxifen and sodium fluoride were each known in the art for treating osteoporosis (see pp. 163 - 164 'Long-Term Menopause Consequences: Osteoporosis Treatment).

Bachmann, G.A. (1994) did not specifically teach wherein the compounds were administered substantially simultaneously, wherein the sodium fluoride was administered from about three months to about three years, wherein the tamoxifen was administered from about three months to about three years without the administration of the second compound during the period of from about three months to about three years or wherein the tamoxifen was administered for a period greater than about three years without the administration of the second compound during the greater than about three year period.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to have beneficial, therapeutic effects on osteoporosis. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

Further, although Bachmann did not specifically state the administration regimens as recited in the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal parameters of treatment because optimal treatment regimens would have been routinely determined in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art do not teach all the various administration techniques recited by the Instant claims, it would be conventional and within the skill of the art to identify

these treatment protocols because the selection of appropriate treatment protocol in order to obtain maximum benefit from pharmaceuticals is conventional and within the skill in the art.

Further, the addition of a carrier to known therapeutic agents does not change the overall effect of the active ingredients, nor does it substantially change the composition as a whole. The addition of carriers to pharmaceutical preparations is routine practice in the art in order to form varying pharmaceutical forms such as pills, capsules, tablets, powders, elixirs or beverages which are all suitable packaging means for the active ingredients of the Instant invention. It would not have required a substantial inventive contribution in order to have added a carrier to a composition comprising tamoxifen and sodium fluoride in order to create any of the above forms of the composition for ease of administration and/or to enhance the manufacturability of the product (to make the product more appealing to the consumer).

Allowable Subject Matter

Claims 3-10 and 13-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 46-50, 52-62, 65-69 and 72 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

11/17/05